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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/595,058   | 01/23/2006  | Tushar A. Kshirsagar | 58884US009          | 1950             |
| 23628 7590 05/22/2008<br>WOLF GREENFIELD & SACKS, P.C.<br>600 ATLANTIC AVENUE<br>BOSTON, MA 02210-2206 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| RODRIGUEZ-GARCIA, VALERIE  |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 4161   |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/595,058

## Applicant(s)

KSHIRSAGAR ET AL.

## Examiner

VALERIE RODRIGUEZ-GARCIA

## Art Unit

4161

**Period for Reply**  
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 18, 20-21, 23, 25-26, 29-32, 34, 36-37, 40, 42-43, 46-49, 63, 95, 97-98, 101, 103-104, 107-109, 111, 134-145 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are 18,20,21,23,25,26,29-32,34,36,37,40,42,43,46-49,63,95,97,98,101,103,104,107-109,111 and 134-145.

### **DETAILED ACTION**

1. This application is a 371 of PCT/US04/26158 filed on 08/12/2004, which claims benefit of provisional application 60/494608 filed on 08/12/20003 and provisional application 60/494605 filed on 08/12/20003.

Claims 1-17, 19, 22, 24, 27, 28, 33, 35, 38, 39, 41, 44, 45, 52-62, 64-94, 96, 99-100, 102, 105-106, 110, 112-133 have been canceled by the Applicant. Claims 138-145 have been added.

Currently, claims 18, 20-21, 23, 25-26, 29-32, 34, 36-37, 40, 42-43, 46-49, 63, 95, 97-98, 101, 103-104, 107-109, 111, 134-145 are pending.

### ***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 18, 20-21, 23, 25-26, 29-32, 34, 36-37, 40, 42-43, 46-49, 63, 134, 138 drawn to compounds or composition of Formula II (claim 18) where R<sub>A</sub> and R<sub>B</sub> form a phenyl ring as in Formula III and V. If this group is elected, a further election of a

single disclosed species is also required. Further restriction based on the election may be made.

Group II, claims 18, 20-21, 23, 25-26, 29-32, 95, 97-98, 101, 103-104, 107-109, 111, 134, 139 drawn to compounds or composition of Formula II (claim 18) where  $R_A$  and  $R_B$  form a heteroaryl ring and the heteroaryl ring is a pyridine ring as in Formula VIII. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group III, claims 18, 20-21, 23, 25-26, 29-31 and 134 drawn to compounds or composition of Formula II (claim 18) where  $R_A$  and  $R_B$  do not form a ring. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group IV, claims 18, 20-21, 23, 25-26, 29-32 and 134 drawn to compounds or composition of Formula II (claim 18) not contained in groups I-III. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group V, claims 135 and 140 drawn to a method of inducing cytokine biosynthesis limited in scope to the compounds of Group I. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group VI, claims 135 and 141 drawn to a method of inducing cytokine biosynthesis limited in scope to the compounds of Group II. If this group is elected, a

further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group VII, claim 135 drawn to a method of inducing cytokine biosynthesis limited in scope to one of the compounds of Group III or IV. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group VIII, claims 136 and 142 drawn to a method of treating a viral disease limited in scope to the compounds of Group I. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group IX, claims 136 and 143 drawn to a method of treating a viral disease limited in scope to the compounds of Group II. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group X, claim 136 drawn to a method of treating a viral disease limited in scope to one of the compounds of Group III or IV. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XI, claims 137 and 144 drawn to a method of treating a neoplastic disease limited in scope to the compounds of Group I. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XII, claims 137 and 145 drawn to a method of treating a neoplastic disease limited in scope to the compounds of Group II. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XIII, claim 137 drawn to a method of treating a neoplastic disease limited in scope to one of the compounds of Group III or IV. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

The inventions listed as Groups I-XIII do not relate to a single general inventive concept under 35 USC 121 or PCT Rule 13.1 because they lack the same or corresponding special technical features:

In the instant case, the special technical feature of Group II is the imidazoquinoline core of formula (VIII), claim 95. The imidazoquinoline core of Group II, does not present a contribution over the prior art because it has been previously disclosed in US 6194425 B1 (column 119, claim 1, supplied in the IDS of 4-18-06). As such, Group II does not share a special technical feature with Group I. Therefore, the claims are not so linked within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I and XIII and between Markush species is broken.

### **Election of Species**

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- Exact Chemical or Compound (All the claims are generic. The species are in the specification.)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Regardless of the Group selected, applicant is required to define a single compound species with an exact chemical structure, no variables, from all the possible structures recited in the claims of the elected group. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. In the instant case, all the claims are generic.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).



The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

a) Each chemical species is a distinct chemical lacking a special technical feature in view of the fact that the core of the chemical is not novel and has been previously disclosed in the prior art (US 6194425 B1).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is *presented prior to* final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable**, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai; In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include all the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.
5. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4161

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VRG

/Patrick J. Nolan/  
Supervisory Patent Examiner, Art Unit 4161